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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,088	01/18/2002	Graham John Hamilton Melrose	2354/141 (FF34527/02)	6479

7590 11/17/2006

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EXAMINER	
KUMAR, PREETI	

ART UNIT	PAPER NUMBER
1751	

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/053,088	MELROSE ET AL.	
	Examiner	Art Unit	
	Preeti Kumar	1751	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-7,9-13,15-17,24-39,42 and 44-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-7,9-13,15-17,24-39,42 and 44-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Request of Correction of Inventorship

1. In view of the papers filed 8/30/2006, the inventorship in this nonprovisional application has been changed by the deletion of Gerry Daly and Damon Matthew Goadby Tilbrook.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Final Rejection

2. Claims 2-7, 9-13, 15-17, 24-39, 42, 44-48 are pending.

Claim 48 is newly added.

Claims 2-5,10, 13, 16-17, 24, 26, 32, 39, 42, 44-46 are amended in the paper filed 8/30/2006.

Response to Amendment

3. The rejection of claims 24-28 and 30-42 under 35 U.S.C. 103(a) as being unpatentable over Melrose et al. (WO 00/03723) is withdrawn in light of applicants amendment to the claims and in light of the request for change of inventorship.

4. The rejection of claims 2-13, 15-17, and 44-47 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Melrose et al. (WO 00/03723) is withdrawn in light of applicants amendment to the claims.

5. The rejection of claims 2-11, 44-45 under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Melrose et al. (WO 01/60874) is withdrawn in light of applicants amendment to the claims.

6. The objection of claim 29 is withdrawn upon further consideration of the prior art. See the new grounds of rejection below.

Response to Arguments

7. Applicant's arguments, filed 8/30/2006, with respect to the rejection(s)of claims 2-7, 9-13, 15-17, 24-39, 42, 44-48 have been fully considered.

Applicants urge that WO 00/03723 is not available as prior art under 35 U.S.C. 102(b) since the subject matter of the limitations of newly presented independent claim 48 and dependent claims 3-7, 9, 10, 13 are entitled to a priority date of February 16, 2000. Examiner acknowledges that the material limitations of at least independent claim 48 is entitled to a priority date of February 16, 2000 which is the filing date of 10/009,139 to which Applicants are claiming a continuation-in-part. Examiner acknowledges Applicants request for change of inventorship. With this request, Applicants go on to state that WO 00/03723 is not available as prior art under 35 U.S.C. 102(a) and cite that a correction has been made to the inventorship to delete Gerry Daly and Damon Matthew Goadby Tilbrook as inventors.

Applicant's arguments have been fully considered but are moot in light of the New Grounds of Rejection below

New Grounds of Rejection

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 2-7, 9-13, 15-17, 24-39, 42, 44-48 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Melrose (WO 96/38186).

Melrose et al. teach a method for the treatment of gastrointestinal disease and/or cancer, and a method of weight gain, via the ingestion of polymeric compositions in humans, animals or birds in need of said treatment. The invention provides methods for the treatment of cancer, the treatment and/or prevention of gastrointestinal disease and/or infection and/or diarrhea and a method for increasing weight gain in humans, animals or birds comprising administering to said humans, animals or birds an effective amount of a pharmaceutical or veterinary composition or feed additive, comprising an effective amount of a polymer and/or copolymer, having the repeating polymeric unit (I) wherein R is H or alkyl, usually C.sub.1 to C.sub.4, or this unit in hydrated, hemiacetal or acetal form, together with a pharmaceutically or veterinarally acceptable carrier, diluent, adjuvant, excipient and/or controlled release system. See abstract.

Melrose et al. teach a method for the preparation of compositions of poly(2-propenal, 2-propenoic acid) comprising the method steps of dissolving the poly(2-

propenal, 2-propenoic acid) in aqueous base, adding an organic compound containing one or more hydrophobic groups, and subsequently acidifying the solution, whereby interaction between the hydrophobic groups of the organic compound and the poly(2-propenal, 2-propenoic acid) prevents precipitation of the poly(2-propenal, 2-propenoic acid) and the solution is consequently stable over a broad pH range. See abstract. Specifically, Melrose et al. teach polymeric compounds having a polyacrolein sub-unit in aldehyde, hydrated, hemi-acetal or acetal form and having biostatic or biocidal properties and the biostatic and/or biocidal uses of these compositions. See page 4, ln.5-10 and page 7,ln.20-25.

Melrose et al. teach a method of producing pellets or like solid composition, the pellets comprising polymers and/or copolymers as defined in the first embodiment of the invention, mainly within a polymeric matrix, said method as defined in the fourth embodiment of the invention and comprising the steps of: (i) dissolving said polymers and/or copolymers in an aqueous alkaline or basic solution; (ii) neutralising said solution with acid; (iii) adding to said neutralised solution insoluble, cross-linked, absorbent polymers of acrylic acid and/or copolymers of acrylamide and acrylic acid, to form wet swollen pellets; and (iv) optionally, wholly or partially drying said wet swollen pellets. The so-formed wet, swollen pellets may be used either wet, partially dried or wholly dried, as an additive to, for example, animal feed. This system is further designed so that the carboxyl-containing groups of the outer polymeric matrix cause the Subject Polymers to remain essentially contained within the matrix when in the acidic environment of the stomach. However, in the alkaline environment of the duodenum,

the carboxyl groups of the matrix become ionised and mutually-repelling, and the pellet rapidly swells to allow the Subject Polymers, aided by repulsion among their own ionic groups, to be excluded by a diffusion process, approximately matching the speed of passage of feed through the duodenum. See page 7, lines 15-35.

Specifically regarding claims 4-11, Melrose teach that the antimircrobial composition comprises pharmaceutically or veterinarally acceptable binders, sweeteners, disintegrating agents, diluents, flavourings, coating agents, preservatives, lubricants and/or time delay agents. Suitable binders include gum acacia, gelatin, corn starch, gum tragacanth, sodium alginate, carboxymethylcellulose or polyethylene glycol. Suitable flavouring agents include peppermint oil, oil of wintergreen, cherry, orange or raspberry flavouring. Suitable coating agents include polymers or copolymers of acrylic acid and/or methacrylic acid and/or their esters, and/or their amides, waxes, fatty alcohols, zein, shellac or gluten. Melrose teach that liquid forms for oral administration may contain, in addition to the above agents, a liquid carrier. Suitable liquid carriers include water, oils such as olive oil, peanut oil, sesame oil, sunflower oil, safflower oil, arachis oil, coconut oil, liquid paraffin, ethylene glycol, propylene glycol, polyethylene glycol, ethanol, propanol, isopropanol, glycerol, fatty alcohols, triglycerides or mixtures thereof. See page 6,ln.15-40..

Specifically regarding claims 12-13, 15 Melrose et al. teach that the antimicrobial composition is added to drinking water. See claim 11.

Specifically regarding claims 16-17, Melrose et al. teach that the composition further comprises one or more of methanol, acetone, tetra-hydrofuran, methyl ethyl

ketone, benzoyl peroxide which exhibit a synergistic increase in antimicrobial activity. See examples 5-15 illustrating compositions comprising 1.5% antimicrobial polymer in 65% ethanol. See line 8 of pg.16.

Regarding claims 4-32 and 36-38, Melrose et al. teach the utility of poly(2-propenal, 2-propenoic acid) in humans, animals such as pigs, birds and mice having microbialogical diseases of the gastrointestinal tract for example E. coli, and organisms such as Staphylococcus aureus, Helicobactor pylori, which cause gastrointestinal disease in animals. See page 8,ln.5-10.

Regarding claims 44-48, Melrose et al. teach the utility of a composition comprising poly(2-propenal, 2-propenoic acid) and polyethylene glycol as an animal feed additive. See abstract and page 7,lines 5-15.

Melrose et al. illustrate in examples 1,13 and 15 a composition comprising 30 mg benzoyl peroxide added to a solution of 1.02 g polyethyleneglycol acrylate and 0.5 ml acrolein in 5 ml methanol. The mixture was stirred and heated to reflux for 48 hours and gave 90% conversion; the residual oil (1.2 g) was chromatographed on Sephadex LH-20 (18 g) in methanol. The structure of the resulting polymer was confirmed by NMR analysis. The Subject Polymers were suspended/dissolved in the drinking water of piglets, at 0.1% w/v for the first 2-3 days and then at 0.05% w/v for the next 7 days; drinking was ad libitum; consumption of Subject Polymers was approximately 200 mg/kg of piglet/day.

Melrose et al. illustrates a composition comprising poly(2-propenal, 2-propenoic acid) in polyethylene glycol which is substantially identical to the material limitations of

the instant claims. Accordingly, the teachings of Melrose et al. anticipate the material limitations of the instant claims.

Alternatively, even if the broad teachings of Melrose et al. are not sufficient to anticipate the material limitations of the instant claims, it would have been nonetheless obvious to one of ordinary skill in the art, to arrive at an antimicrobial composition comprising a derivative of poly(2-propenal, 2-propenoic acid) in polyethylene glycol having protected carbonyl groups and reduction of H^1NMR signal as recited by the instant claims, because Melrose et al. teach a reaction of the subject polymers poly(2-propenal, 2-propenoic acid) with polyethylene glycol at room temperature upto 100 degrees C to increase hydrophilicity and utility in the application of treating diseases of the gastrointestinal tract of humans, animals and birds. See page 3,ln.25-35.

Furthermore, limitations to protected carbonyl groups and reduction in H^1NMR signal are encompassed by the invention of Melrose et al. because Melrose et al. illustrate by example the use of similar materials (i.e. poly(2-propenal, 2-propenoic acid)) and in the similar production steps (i.e. reaction with polyethylene glycol) to produce an antimicrobial composition which have the claimed intended use in treating diseases of the gastrointestinal tract of humans, animals and birds. The same components in the same composition would result in the same property of H^1NMR signal reduction and the carbonyl groups being protected. The burden is upon the applicant to prove otherwise. *In re Fitzgerald*, 205 USPQ 594.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 2-7, 10, 13, 16, 17, 24-25, 28, 30-31, 42, and 46-48, are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10, 18, 22, 24 and 28 of U.S. Patent No. 6,410,040. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 10, 18, 22, 24 and 28 of US Patent No. 6,410,040 encompass the material limitations of a polymeric antimicrobial composition and a method of treating an animal with a antimicrobial composition comprising the same reaction product between poly(2-propenal, 2-propenoic acid) and an organic compound containing one or more hydroxyl groups as recited by the instant claims.

12. Claims 2-7, 9-13, 15-17, 24-39, 42, and 44-48 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,723,336. Although the conflicting claims are not identical, they are

not patentably distinct from each other because claims 1-36 of US Patent No. 6,723,336 encompass the material limitations of a polymeric antimicrobial composition and a method of treating an animal with a antimicrobial composition comprising the same reaction product between poly(2-propenal, 2-propenoic acid) and an organic compound containing one or more hydroxyl groups as recited by the instant claims.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Preeti Kumar whose telephone number is 571-272-1320. The examiner can normally be reached on M-F 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas Mc Ginty can be reached on 571-272-1029. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Preeti Kumar PK.
Examiner
Art Unit 1751

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1751